

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

Track Three

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**PHARMACY DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO
EXCLUDE CARMEN CATIZONE**

This Court should exclude all or part of the opinion of Carmen Catizone. Mr. Catizone's methodology—as described in his original report, his supplemental report, and at his deposition—is unreliable. His attempt to mechanistically identify “red flags” is unreliable, and he has made no attempt to test whether it actually identifies prescriptions that are likely to be diverted. *E.g.*, Ex. A, 6/15/2021 Catizone Tr. at 218:14-19 (agreeing that his methodology flagged prescriptions that were not truly subject to red flags).¹

Even if his opinion is not excluded in its entirety, Mr. Catizone's opinion should be limited in two respects. First, Mr. Catizone should not be permitted to testify that the prescriptions flagged by his methodology were not written for a legitimate medical purpose. As Mr. Catizone admits, the fact that a prescription was flagged by his analysis does not mean that prescription was written for an illegitimate purpose. *Id.* at 167:3-7. This is a crucial fact, 21 C.F.R. § 1306.04, and he should not be permitted to expand his opinion at trial.

¹ Pharmacy Defendants anticipate that Mr. Catizone will provide a supplemental opinion after reviewing the notes fields and prescription-specific documentation. They anticipate challenging any new opinions with a supplemental Daubert motion.

Second, Mr. Catizone’s testimony about diversion of opioids is wholly speculative and not supported by his background, experience, or qualifications. Mr. Catizone assumes that drug overdose rates and the overall volume of opioids in Lake and Trumbull Counties somehow demonstrates the diversion of opioids dispensed by Pharmacy Defendants, but he offers no support for this connection, admits that this methodology fails to detect the most common form of diversion, never attempted to quantify the number of diverted opioids, and has no background or qualifications that would allow him to reliably opine on the percentage of diverted opioids. At a minimum, the opinion regarding diversion should be excluded.

BACKGROUND

Carmen Catizone is the former Executive Director and the CEO of the National Association of Boards of Pharmacy (NABP). Rep. 4. As Executive Director he oversaw the day-to-day operations of the NABP. Ex. B, Expert Report of Carmen Catizone at 4. He spent only two years working full-time as a pharmacist—between 1983 and 1985, Ex. A, 6/15/2021 Catizone Tr. at 87:8-13—and never worked as a pharmacist in Ohio. *Id.* at 88:19-20.

Mr. Catizone’s testimony concerns the corresponding responsibility of pharmacists not to fill prescriptions for opioid medications written for no legitimate medical purpose. He identified the “list and description of certain red flags of diversion,” Ex. B, Expert Report of Carmen Catizone at 32, that Dr. McCann applied to the prescriptions dispensed by Pharmacy Defendants to flag prescriptions as subject to red flags.² Mr. Catizone testified that pharmacists had an

² As detailed in the Motion to Exclude the Opinions and Testimony of Craig McCann, Dr. McCann (and thus Mr. Catizone’s supplemental report) does not actually identify prescriptions flagged by Mr. Catizone’s 16 “red flags”—he identifies prescriptions flagged both by Mr. Catizone’s 16 red flags and by one of the original 27 “red flags” from Plaintiffs’ counsel.

obligation before dispensing to investigate every prescription that flagged to determine that it is legitimate.

Critically, as discussed below, Mr. Catizone did not testify that these flagged prescriptions were medically illegitimate, and although he speculates that a significant portion of these flagged prescriptions were diverted, he has neither a reliable basis nor any qualifications that would allow him to offer this opinion.

ARGUMENT

I. Mr. Catizone Applies an Unreliable and Untested Methodology.

Mr. Catizone opines that Pharmacy Defendants “fill[ed] thousands of prescriptions presenting significant red flags.” Rep. at 104. He attempts to identify these prescriptions mechanistically, applying bright-line rules and flagging all prescriptions that meet one of his tests, without regard to any context or other information about the prescriptions.

His tests are admittedly arbitrary. For example, Mr. Catizone testifies that “distance is a red flag.” Ex. C, 6/16/2021 Catizone Tr. at 399:11. To test for this, he selected “25 miles [a]s a parameter that, as I’ve determined, is a safe parameter to utilize.” *Id.* at 399:12-13. But, Mr. Catizone acknowledged, other pharmacists might use different tests: “[A] pharmacist may, in their professional and independent judgment, make a determination that 30 miles or 20 miles may not be a red flag.” *Id.* at 399:13-14. Mr. Catizone admits that some prescriptions flagged by the distance metrics “are not really red flags.” Ex. A, 6/15/2021 Catizone Tr. at 217-218; *see also id.* at 159:22-160:11 (testifying that he needed to review additional information to determine whether there was “in fact, a red flag” or whether “it really wasn’t a red flag”).

In fact, Mr. Catizone freely agrees that his methodology erroneously identifies some prescriptions as having red flags:

Q. You would agree that there are going to be some prescriptions that were flagged under these flags that fall within these exceptions [and thus are not really red flags]? You're just saying that you can't identify them; is that right?

A. Yes, sir.

Id. at 218:14-19; *see also* Ex. C, 6/16/2021 Catizone Tr. at 509:23-510:1 (“[H]ow many of those were actually red flags, I don’t have that information[.]”).

As the Supreme Court explained in *Daubert* itself, in considering the admissibility of an expert’s testimony, courts must consider the methodology’s “known or potential rate of error” and “whether it can be (and has been) tested.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993).

Mr. Catizone admits that there is some rate of error attached to his methodology: it incorrectly flags some prescriptions as having red flags. But the error rate is unknown because Mr. Catizone has never attempted to test his methodology. He never reviewed the specific prescriptions flagged by his methodology to determine whether those prescriptions were—or were not—more likely to be diverted than other prescriptions. With no testing, Mr. Catizone’s methodology is unreliable, and his testimony should be excluded.

II. Mr. Catizone Should Not be Permitted to Testify that Flagged Prescriptions Were Not Written for a Legitimate Medical Purpose.

Even if it were reliable, Mr. Catizone’s methodology regarding red flags does not purport to identify which, if any, of these prescriptions were written for illegitimate medical purposes:

Q. Would you agree with me that just because a prescription flags under one of your 16 red flags, that does not mean that it was written for an illegitimate medical purpose?

A. Yes, sir.

...

Q. And you haven't made any effort to determine how many of the prescriptions that flagged under your 16 red-flag methodologies were not written for a legitimate medical purpose?

A. Not individually, sir.

Ex. A, 6/15/2021 Catizone Tr. at 167:3-7, 20-21.

Q. [Y]our opinion is that 70 to 90 percent of those 37,066 prescriptions were written for an illegitimate reason?

A. No, sir. . . . [L]acking the documentation, I cannot quantify whether or not those 37,000 prescriptions fell into that category.

Ex. C, 6/16/2021 Catizone Tr. at 418:10-19; *see also* Ex. A, 6/15/2021 Catizone Tr. at 212:16-20 (denying that his methodology—specifically, the 25-mile test—was “trying to identify prescriptions that are likely to have been written for an illegitimate medical purpose or to be diverted”); *id.* at 238:14-18 (agreeing that a prescription for a combination of drugs flagged by his methodology “might be a danger to the patient” but “not be an illegitimate prescription”).

Given these acknowledgments at his deposition, this Court should make clear that Mr. Catizone's testimony should be limited to opining about prescriptions *potentially* subject to red flags. He should not be permitted to suggest that these prescriptions were (or were likely to have been) written for an illegitimate medical purpose, an opinion that he has not given and would not have a reliable basis to give.

III. Mr. Catizone's Testimony About Diverted Prescriptions Is Unreliable and Speculative.

At his deposition, Mr. Catizone also offered an opinion regarding the number of flagged prescriptions that were diverted: “[B]ased upon the other data that I reviewed, a significant number of those prescriptions were diverted.” Ex. A, 6/15/2021 Catizone Tr. at 161:3-5. But Mr. Catizone admitted that his methodology fails to identify prescriptions that were actually diverted:

Q. And would you agree with me that it [the presence of a flag] also does not mean that the drugs that were dispensed to fill that prescription were diverted?

A. Yes, sir.

Id. at 167:8-11. He made no attempt to quantify which, if any flagged prescriptions were actually diverted:

Q. And you have not made any effort in your -- if you have, tell me. But as I understand it, you've not made any effort to determine how many of the prescriptions that flagged under your flags 1 through 16 were actually diverted?

A. Not the individual numbers, sir, no.

Id. at 167:12-18.

Mr. Catizone did not purport to identify how many prescriptions were diverted in Lake and Trumbull Counties. Nor did he identify how many of these diverted prescriptions were prescriptions that he flagged.

Instead, Mr. Catizone bases his ipse dixit speculation regarding diversion on the total number of opioids—including prescriptions written for legitimate medical purposes—dispensed in Lake and Trumbull Counties from all sources and “the number of people who died from drug overdoses” (without any regard to the cause of those overdoses or any attempt to link them to opioids dispensed by Pharmacy Defendants). *Id.* at 174:8-9. But Mr. Catizone offers no basis for his assumption that the number of drug overdoses correlates directly with diversion of prescription opioid medication, and nothing in his background, experience, or education qualifies him to testify about any link between the number of overdoses (or overall number of dispensed opioids) and the number of diverted opioid prescriptions.

To the contrary, at his deposition, Mr. Catizone admitted that his methodology could not detect diversion “that occurs after a prescription is dispensed because the patient who received the prescription gives some of it to family members or friends.” *Id.* at 172:10-20 (“[N]one of the red flags identify that activity.”). Nor was Mr. Catizone familiar with studies indicating that this form of diversion was the most common form: “I would have no way or no reason to disagree with it,

sir.” *Id.* at 173:12-13. Indeed, he “would agree with those statistics” showing “that approximately 70 percent of people who report nonmedical use of prescription medications, including opioid pain relievers, say that they got their drugs from a friend or family member.” *Id.* at 173:15-174:1.

Mr. Catizone has neither the expertise nor any reliable basis to opine regarding the number of flagged prescriptions that were actually diverted. This Court should exclude his opinions about diversion of opioids as speculative, not based on any reliable methodology, and outside the scope of his qualifications.

For these reasons, Mr. Catizone’s testimony should be excluded or limited, as set forth above.

Dated: July 23, 2021

Respectfully submitted,

/s/ John M. Majoras
John M. Majoras
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
Phone: (202) 879-3939
Email: jmmajoras@jonesday.com

Tina M. Tabacchi
Tara A. Fumerton
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
E-mail: tmtabacchi@jonesday.com
E-mail: tfumerton@jonesday.com

Attorneys for Walmart Inc.

/s/ Alexandra W. Miller (consent)
Alexandra W. Miller
Eric R. Delinsky
ZUCKERMAN SPAEDER LLP
1800 M Street, NW

Suite 1000
Washington, DC 20036
Phone: (202) 778-1800
E-mail: smiller@zuckerman.com
E-mail: edelinsky@zuckerman.com

Attorneys for CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores, L.L.C.

/s/ Robert M. Barnes (consent)

Robert M. Barnes
Scott D. Livingston
Joshua A. Kobrin
MARCUS & SHAPIRA LLP
35th Floor, One Oxford Centre 301 Grant Street
Pittsburgh, PA 15219
Phone: (412) 471-3490
Email: rbarnes@marcus-shapira.com
Email: livingston@marcus-shapira.com
Email: kobrin@marcus-shapira.com

Attorneys for Giant Eagle and HBC Service Company

/s/ Kelly A. Moore (consent)

Kelly A. Moore
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Phone: (212) 309-6612
E-mail: kelly.moore@morganlewis.com

Elisa P. McEnroe
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Phone: (215) 963-5917
Email: elisa.mcenroe@morganlewis.com

Attorneys for Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center

/s/ Kaspar J. Stoffelmayr (consent)

Kaspar J. Stoffelmayr

Brian C. Swanson

Katherine M. Swift

Sharon Desh

Sten A. Jernudd

BARTLIT BECK LLP

54 West Hubbard Street

Chicago, Illinois 60654

Phone: (312) 494-4400

E-mail: kaspar.stoffelmayr@bartlitbeck.com

E-mail: brian.swanson@bartlitbeck.com

E-mail: kate.swift@bartlitbeck.com

E-mail: sharon.desh@bartlitbeck.com

E-mail: sten.jernudd@bartlitbeck.com

Alex J. Harris

BARTLIT BECK LLP

1801 Wewatta Street, Suite 1200

Denver, Colorado 80202

Phone: (303) 592-3100

E-mail: alex.harris@bartlitbeck.com

*Attorneys for Walgreens Boots Alliance, Inc.,
Walgreen Co. and Walgreen Eastern Co., Inc.*